#### REMARKS

This responds to the Office Action dated April 19, 2005.

Original claims 1-16 were rejected. No claims were allowed.

This amendment cancels claims 5, 10, 11, 14 and 15.

The independent claims of the application have been amended and are believed to adequately distinguish over the prior art.

### **Background**

The airway disclosed and claimed in this application is used for intubating patients that may be under heavy sedation. When a small child or infant is sedated, it is difficult to maintain the proper level of sedation, and over-sedation can result in death of the patient.

One of the ways for determining the health of the patient is to monitor the breath exhaled from the patient and measure the end-tidal carbon dioxide. As the carbon dioxide of the exhaled breath increases, this indicates that the patient may not be breathing properly, not getting enough oxygen in its breath, or possibly other physical difficulties.

The airway disclosed by the applicant is an improvement over the prior art, including over applicant's prior Canadian patent 1,161,720. Applicant has included an enlarged area, the plenum 50 as shown in Fig. 3, at the proximal end of the airway 12. This enlarged internal area of the air passages through the airway provides for an accumulation of a larger volume of air that is exhausted from the lungs of the patient. The plenum 50 is positioned along the airway at a location that will be outside of the throat and mouth of the patient. Therefore, the distal arcuate section 18 of the elongated body 14 that is received through the mouth and throat of the patient will not have to be enlarged to provide the plenum. Indeed, the use of the plenum may allow for the use of an airway that is of smaller breadth than taught in the prior art since the same or even greater accumulation of exhaled breath may be retained in the airway.

The plenum provides an area of the airway that causes the breath being expelled from the patient to slow in its velocity of movement before it is moved through the open passageway 36 or through the nipple 32. The physician has the choice of closing the nipple 32 with his or her thumb and redirecting the expelled breath from the plenum 50 through the conduit 46 to the monitor 40, so as to substantially purge the conduit and monitor of air with the exhaled breath.

With the nipple 32 closed, only expelled breath will move through the plenum 50 to the monitor. In the meantime, the patient can continue to inhale by drawing in air from the outside along the external conduits 24 that are formed by the flanges 20, 22 of the elongated body 14 of the airway 12.

The plenum is preferably from two to four times the breadth of the open-ended passage 26 of the elongated body 14 and of the passage 33 through the nipple 32.

Another benefit of the enlarged plenum is that should the breath expelled from the patient carry with it mucus from the throat or lungs, the larger plenum causes the velocity of the expelled breath to slow before it is exhausted toward the open-ended passage 36 of the radially extending conduit section 34. This tends to cause the mucus to slow its movement and drop to the lower surface of the plenum, avoiding passage to the monitor. Further, the right angle turn through the plenum enhances the fall out of the liquid mucus.

All of this is accomplished without enlarging the outside breadth of the elongated body 14 of the airway, so that the elongated body can be moved through the throat of the patient with a minimum of aggravation into the throat of the patient.

### **Priority**

Applicant has entered the notation in the specification that the priority application is now abandoned.

# **Drawings**

The drawings of the application were objected to because they do not include the numeral 50 leading to the dash line, as stated in the specification.

The specification has been amended so that the dash line is recited as number 47. This corresponds to the drawings.

Applicant notes that the numeral 28 in Fig. 4 is incorrect. The numeral 28 has been changed to --27-- in the drawing, Sheet 1. This avoids the multiple use of the numeral 28 in the drawings and in the specification.

### **Specification**

The specification is objected to because of the multiple use of the numeral 28. The drawing has been changed so as to change the numeral 28 in Fig. 4 to 27. The numeral 30 has been changed to 29 when designating the side ports of the elongated body 14.

## Claim Rejections - 35 U.S.C. § 103

Claims 1-7 and 12-16 were rejected under § 103(a) as being unpatentable over <u>Wall</u> (Canadian 1,161,720) in view of <u>Schaller</u> (5,555,890). The Canadian patent discloses applicant's prior invention. The Canadian patent does not include the plenum or the monitor of applicant's invention. <u>Schaller</u> discloses the use of a means for measuring a fluid 32, such as measuring the end-tidal CO<sub>2</sub> and a means for measuring the fluid 32 is a CO<sub>2</sub> sensor, such as a capnograph.

It is noted that <u>Schaller</u> has a "suction trap" 24 for catching any secretions that would be sucked into the catheter.

Schaller requires the additional suction trap that is located externally of the patient in order to accommodate secretions from the patient. Applicant's airway has a plenum 50 that is part of the airway, and the plenum is located exteriorly of the patient so that it can be of a larger size without requiring a larger breadth elongated body 14 that is to be received in the patient's throat.

There is no suggestion that <u>Schaller</u> would provide a plenum on its airway, or that <u>Schaller</u> would suggest that a plenum be provided on the airway of the Canadian patent.

Claim 1 and its dependent claims include the limitation of the plenum being formed on the airway, and the air from the patient exhaled through the plenum.

Independent claim 6 is an apparatus claim and sets forth the plenum for accumulating the exhaled breath of the patient positioned at the radially extending conduit for placement outside the patient's mouth. The plenum is also described as being in communication with both the openended passage of the elongated body and the passage of the radially extending conduit, with the plenum being of larger breadth than either the passage of the radially extending conduit or the openended passage of the elongated body. This provides some of the advantages described hereinbefore.

Dependent claims 7 and 13 describe the airway being constructed of thermoplastic polymer. This feature of the airway allows its use during electrocardiograms, where the use of metal is not allowed. Children and infants generally usually are difficult to handle during electrocardiograms unless they are sedated. It is important to intubate the children and infants during sedation so as to avoid strangulation. The use of the enlarged plenum on the airway is another safeguard against strangulation.

Claims 8 and 9 concern the color application to the airway. This is important because of the significant size differences of patients that might be intubated. Claims 8 and 9 were rejected as being unpatentable over Wall/Schaller as applied to claim 1, and further in view of Linden (4,882,867). However, Linden discloses dental tools that have different functions, and the functions are identified by different colors. By contrast, applicant's airways are of the same function, but different sizes. The rings of Linden are constructed so as to withstand autoclaving and other general abuse, whereas applicant's airways are to be discarded after use.

Claims 10 and 11 are cancelled.

Independent claim 12 sets forth the T-connection formed between the nipple and the protrusion and the orifice extending through the T-connection to the passageway of the airway. The T-connection is for controlling the movement of breath exhaled from the patient through the passage. The orifice at the T-connection is of at least twice greater in cross sectional area than the central passage of the airway, and forms a plenum for accumulating the exhaled breath of the patient. As described above, this provides advantages not suggested or taught by the applied references.

Claims 14 and 15 are cancelled.

Independent claim 16 also sets forth the features of the T-connection formed at the nipple, with the T-connection forming a plenum of a breadth at least twice as large as the breadth of the airway for receiving the exhaled breath of the patient. This is not described in the applied references and provides the advantages described above.

Applicant submits that the claims remaining in the application now adequately distinguish over the prior art. Favorable reconsideration of the application is requested.

Respectfully submitted,

George M. Thomas, Reg. No. 22,260

THOMAS, KAYDEN, HORSTEMEYER & RISLEY, L.L.P.

Suite 1750 100 Galleria Parkway N.W. Atlanta, Georgia 30339 (770) 933-9500